Suggested Format for Residue Chemistry Study Reports

Residue Analytical Method

OPPTS 860.1340

The purpose of this document is to suggest the format for final reports (right column) and to provide instructions for creation of Adobe PDF electronic submission documents (left column). The format is modeled after the NAFTA Data Evaluation Record template that will be used by OPP's and PMRA's scientists when this type of study is reviewed. The format is in outline form. The study report will include text and standard tables (detailed below).

Regarding PDF, both 'bookmarks' and 'links' are referenced. Bookmarks and links are similar in function in that both provide the reader with a way to move efficiently through a document as well as across documents. Bookmarks are a type of link that appear in the navigation pane on the left side of the PDF Reader user screen. Links appear within the body of a document as blue text. They permit the reader to jump to other locations with related information in the same document or other electronic documents.

Residue Chemistry Study Reports – RESIDUE ANALYTICAL METHOD	
Instructions to create PDF	**Document Format**
Create Bookmarks for each item in document format column.	• Study Title Page. • Statement of Data Confidentiality *No confidentiality claims can be made for electronically submitted studies at this time.* • GLP Statement. • QA Statement. • Table of Contents
Create links in summary to related text and tables in body of study report or appendices	• Executive Summary. - Summary of Background Information & Experimental Design. - Summary of Results.
Create links to related tables	• Background Information, Materials and Methods. - Background Information – See Tables 1 and 2. - Materials and Methods – See Tables 3 and 4. • Results and Discussion – See Tables 5 - 9

TABLE FORMATS

Tables should be imported into the PDF document from their native formats. See OPP's detailed technical specifications for creating PDF for details.

Table 1 – Test Compound Nomenclature.

Compound	Chemical Structure
Common name	
Company experimental name	
IUPAC name	
CAS name	
CAS #	
End-use product/EP	

Table 2 – Physicochemical Properties.

Parameter	Value	Reference
Melting point/range		
pH		
Density		
Water solubility (__°C)		
Solvent solubility (mg/L at __°C)		
Vapor pressure at __°C		
Dissociation constant (pK_a)		
Octanol/water partition coefficient Log (K_{ow})		
UV/visible absorption spectrum		

Table 3 – Summary Parameters for the Analytical Method Used for the Quantitation of [*chemical*] Residues in [*matrices*].

Method ID	
Analyte(s)	
Extraction solvent/technique	
Cleanup strategies	
Instrument/Detector	
Standardization method	
Stability of std solutions	
Retention times	

Table 4 – Summary Parameters for the Analytical Enforcement Method Used for the Quantitation of [*chemical*] Residues in [*matrices*].

Method ID	
Analyte(s)	
Extraction solvent/technique	
Cleanup strategies	
Instrument/Detector	
Standardization method	
Stability of std solutions	
Retention times	

Table 5 – Recovery Results form Method Validation of [*matrices*] using the Data-Gathering Analytical Method. Standards were prepared in [*solvent*].

Matrix	Spiking level (mg/kg)	Recoveries obtained	Mean recovery ± SD (CV)

Table 6 – Characteristics for the Data-Gathering Analytical Method Used for the Quantitiation of [*chemical*] Residues in [*matrices*].

Analyte	
Equipment ID	
Limit of quantitation (LOQ)	
Limit of detection (LOD)	
Accuracy/Precision	*[range of percent recoveries ± coefficient of variation (specify range) indicating acceptable/unacceptable accuracy/precision in the range of spiking levels (x)]*
Reliability of the method (ILV)	*[An independent laboratory method validation [ILV], method no. AAA, was conducted to verify the reliability of method no. AAA for the determination of (pesticide) residues in [matrices]. The values obtained are indicative that method no. AAA is reliable.]*
Linearity	*[The method/detector response was linear (coefficient of determination, r^2 = 0.xxx) within the range of xxx - yyy ppm.]*
Specificity	*[The control chromatograms generally have no peaks above the chromatographic background and the spiked sample chromatograms contain only the analyte peak of interest. Peaks were well defined and symmetrical. There appeared to be no carryover to the following chromatograms.]*

Table 7 – Recovery Results from Method Validation of [matrices] using the <u>Enforcement</u> Analytical Method. Standards were prepared in [solvent].

Matrix	Spiking level (mg/kg)	Recoveries obtained	Mean recovery ± SD (CV)

Table 8 – Characteristics for the Enforcement Analytical Method Used for the Quantitiation of [*chemical*] Residues in [*matrices*].

Analyte	
Equipment ID	
Limit of quantitation (LOQ)	
Limit of detection (LOD)	
Accuracy/Precision	*[range of percent recoveries ± coefficient of variation (specify range) indicating acceptable/unacceptable accuracy/precision in the range of spiking levels (x)]*
Reliability of the Method (ILV)	*[An independent laboratory method validation [ILV], method no. AAA, was conducted to verify the reliability of method no. AAA for the determination of (pesticide) residues in [matrices]. The values obtained are indicative that method no. AAA is reliable.]*
Linearity	*[The method/detector response was linear (coefficient of determination, r^2 = 0.xxx) within the range of xxx - yyy ppm.]*
Specificity	*[The control chromatograms generally have no peaks above the chromatographic background and the spiked sample chromatograms contain only the analyte peak of interest. Peaks were well defined and symmetrical. There appeared to be no carryover to the following chromatograms.]*

Table 9 – Recovery Results Obtained by an Independent Laboratory Validation of the Enforcement Method for the Determination of [*chemical*] in [*matrices*].

Matrix	Spiking level (µg/g)	Recoveries obtained	Mean recovery ± SD (CV)